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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,966	05/10/2001	Rima Kaddurah-Daouk	AVZ-020CN	5588

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EXAMINER	
WESTERBERG, NISSA M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/852,966	KADDURAH-DAOUK, RIMA	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68 - 70, 72, 73, 82 - 85, 88 - 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68 - 70, 72, 73, 82 - 85, 88 - 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's arguments, filed September 2, 2008, have been fully considered. The following rejections and/or objections constitute the complete set presently being applied to the instant application

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 68 – 70, 84, 85, 88 and 92 – 94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5, 9 and 25 – 29 of U.S. Patent No. 6,242,491 further in view of Ozlen (US 5,441,740). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application recite the administration of a composition comprising an effective amount of creatine or a salt thereof and a skin preserving agent, such as EDTA, to a patient suffering from skin disorder such as skin wrinkles.

The claims of '491 recite a method for treating skin damage such as that which results from wrinkles, by administration of a composition comprising an effective amount of creatine, creatine phosphate or a salt thereof.

The claims of '491 do not recite the inclusion of a skin preserving agent such as EDTA.

Ozlen discloses a topical composition comprising alpha hydroxy acids, salicylic acid, bromelian, papain and disodium EDTA (col 3, ln 50 – col 4, ln 18) for treating skin conditions such as dry skin and wrinkles (col 1, ln 47 – 51).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and apply a composition comprising creating for the treatment of wrinkles, as taught by '491 and EDTA, a constituent of the topical wrinkle formulation taught by Ozlen. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

4. Claims 68 – 70, 84, 85, 88 and 92 – 94 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 5 and 7 – 10 of U.S. Patent No. 7,186,754 further in view of Ozlen (US 5,441,740). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application recite the administration of a composition comprising an effective amount of creatine or a salt thereof and a skin preserving agent, such as EDTA, to a patient suffering from skin disorder such as skin wrinkles.

The claims of '754 recite a method for treating uneven pigmentation of the skin, by administration of a composition comprising an effective amount of creatine, creatine phosphate or a salt thereof.

The claims of '754 do not recite the inclusion of a skin preserving agent such as EDTA.

Ozlen discloses a topical composition comprising alpha hydroxy acids, salicylic acid, bromelian, papain and disodium EDTA (col 3, ln 50 – col 4, ln 18) for treating skin conditions such as dry skin and wrinkles (col 1, ln 47 – 51). This composition can also result in the fading of age spots (col 4, ln 44), which appear as the result of uneven pigmentation of the skin.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and apply a composition comprising creating for the treatment of wrinkles or other skin disorders such as uneven pigmentation such as age spots, as taught by '754 and EDTA, a constituent of the topical wrinkle formulation taught by Ozlen. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

5. Claims 68 – 70, 73, 84, 85 and 89 – 94 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1

– 5, 6, 12 and 13 of copending U.S. Patent Application No. 11/649145 further in view of Ozlen (US 5,441,740). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the instant application recite the administration of a composition comprising an effective amount of creatine or a salt thereof and a skin preserving agent, such as EDTA, to a patient suffering from skin disorder such as skin wrinkles.

The claims of '145 recite a method for treating uneven pigmentation of the skin by administration of a composition comprising an effective amount of creatine compounds, such a creatine, creatine citrate or creatine ascorbate.

The claims of '145 do not recite the inclusion of a skin preserving agent such as EDTA.

Ozlen discloses a topical composition comprising alpha hydroxy acids, salicylic acid, bromelian, papain and disodium EDTA (col 3, ln 50 – col 4, ln 18) for treating skin conditions such as dry skin and wrinkles (col 1, ln 47 – 51). This composition can also result in the fading of age spots (col 4, ln 44), which appear as the result of uneven pigmentation of the skin.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and apply a composition comprising creating for the treatment of wrinkles or other skin disorders such as uneven pigmentation such as age spots, as taught by '145 and EDTA, a constituent of the topical wrinkle formulation taught by Ozlen. This composition will also treat uneven pigmentation as the same composition is topically applied. "It is prima facie obvious to combine two compositions

each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 68 – 70 were rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (US 5,702,688). In view of the amendments to the claims submitted September 2, 2008, this rejection is WITHDRAWN.

8. Claims 68 – 70 were rejected under 35 U.S.C. 102(b) as being anticipated by Kaddurah-Daouk et al. (WO 96/14063) In view of the amendments to the claims submitted September 2, 2008, this rejection is WITHDRAWN.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 68 – 70, 82, 84, 85, 88 and 92 – 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 5,702,688) in view of Ozlen (US 5,441,740).

Yu discloses the treatment of cosmetic and dermatological conditions such as wrinkles (abstract). The compositions used in these methods can include creatine (col 34, ln 3 – 7). These compositions can be administered topically (col 1, ln 16 – 19). The compositions can also include sunscreen agents (col 12, ln 63).

However, Yu et al. does not disclose the use of a composition comprising creatine or a salt thereof and a skin preserving agent selected from the Markush group present in claims 68 – 70.

Ozlen discloses a topical composition comprising alpha hydroxy acids, salicylic acid, bromelian, papain and disodium EDTA (col 3, ln 50 – col 4, ln 18) for treating skin conditions such as dry skin and wrinkles (col 1, ln 47 – 51).

It would have been obvious to one of ordinary skill in the art to combine the creatine containing composition taught by Yu et al. with the EDTA containing composition taught by Ozlen as both topical compositions are suitable for the treatment of wrinkles and topically applying the composition. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**.

As put forth in the Board decision mailed July 2, 2008, the failure of Yu et al. to appreciate the benefit provided by creatine is immaterial to the question of anticipation (p 5, last paragraph). Therefore, as the active steps of the method are the same (administration of a topical composition comprising creatine and EDTA), the requirements of the method (e.g., increasing energy reserves in the skin or sustaining energy production in the skin) is necessarily met.

13. Claims 68 – 70, 73, 82 – 85, 88 and 92 – 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. and Ozlen as applied to claims 68 – 70, 82, 84, 85, 88 and 92 – 94 above, and further in view of Fujimura (US 5,939,078).

Yu et al. and Ozlen disclose a composition comprising creatine and EDTA for the topical treatment of skin conditions such as wrinkles, which can contain sunscreen agents.

Neither reference discloses the use of creatine citrate. While Yu et al. indicates the sunscreen agents may be included in the composition, no examples of such agents are given.

Fujimura et al. discloses a wrinkle care product (abstract). The product comprises compound 8 (creatine; col 8) or an acid addition salt such as citric acid (col 3, ln 22) of the guanidine derivative. That acid addition salt would be creatine citrate. Fujimura et al. also discloses that inorganic powders for UV protection (sunscreens) such as zinc oxide or titanium oxide can be present in the wrinkle care product (col 6, ln 49 – 51).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and apply a topical composition comprising creatine and EDTA as taught by Yu et al. and Ozlen for the treatment of wrinkles and use creatine citrate as the creatine ingredient, taught by Fujimura et al. as a creatine salt that is useful for the treatment of wrinkles. Fujimura et al. also provides examples of zinc oxide and titanium oxide as sunscreen agents in the composition used in the method.

14. Claims 68 – 70, 82, 84, 85 and 88– 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. and Ozlen as applied to claims 68 – 70, 82, 84, 85, 88 and 92 – 94 above, and further in view of Pischel et al. (US 5,863,939).

Yu et al. and Ozlen disclose a composition comprising creatine and EDTA for the topical treatment of skin conditions such as wrinkles, which can contain sunscreen agents.

Neither reference discloses the use of creatine ascorbate.

Pischel et al discloses that while creatine has many useful properties (col 1, 37 – 50), creatine salts often decompose into creatinine, but that creatine ascorbates do not decompose over time to form this product and therefore have a long shelf life (col 1, ln 10 – 12).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and apply a topical composition comprising creatine and EDTA as taught by Yu et al. and Ozlen for the treatment of wrinkles and use creatine

ascorbate, as Pischel et al. teaches that this creatine salt has a longer shelf life and does not decompose into creatinine.

15. Claims 68 – 70, 72, 82, 84, 85, 88 and 92 – 94 rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. and Ozlen as applied to claims 68 – 70, 82, 84, 85, 88 and 92 – 94 above, and further in view of Almada et al. (US 5,627,172).

Yu et al. and Ozlen disclose a composition comprising creatine and EDTA for the topical treatment of skin conditions such as wrinkles, which can contain sunscreen agents.

Neither reference discloses the use of creatine monohydrate.

Almada et al. discloses that a number of forms of creatine can be used to produce the physiologic effect, including creatine monohydrate, pharmaceutically acceptable creatine salts or complexes such as creatine hydrochloride or creatine phosphate.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare and apply a topical composition comprising creatine and EDTA as taught by Yu et al. and Ozlen for the treatment of wrinkles and use creatine monohydrate, taught by Almada et al. as creatine salts which are physiologically active.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW